**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF TEXAS**
**BROWNSVILLE DIVISION**

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| CELA MORA,<br><br>Plaintiff,<br><br>vs.<br><br>ANGIODYNAMICS, INC., & NAVILYST MEDICAL, INC.,<br><br>Defendants. | Case No.: 1:21-cv-00199<br><br>**COMPLAINT FOR DAMAGES**<br><br>**(1) NEGLIGENCE.**<br>**(2) FAILURE TO WARN**<br>**(3) MANUFACTURING DEFECT**<br>**(4) DESIGN DEFECT**<br>**(5) BREACH OF IMPLIED WARRANTY**<br>**(6) BREACH OF EXPRESS WARRANTY**<br><br>**DEMAND FOR JURY TRIAL** |

COMES NOW the Plaintiff, CELA MORA, (who hereinafter shall be referred to as the "Plaintiff" or as "MORA"), by and through her undersigned counsel, and brings this Complaint against AngioDynamics, Inc. and Navilyst Medical, Inc. (collectively, the "Defendants"), and alleges as follows:

1. This is an action for damages arising out of the failure relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective implantable vascular access device sold under the trade name of SmartPort (hereinafter "SmartPort", or "Defective Device").

## PARTIES

2. Plaintiff, CELA MORA, is an adult resident of Cameron County, Texas and claims damages as set forth below.

3. Defendant AngioDynamics, Inc. ("AngioDynamics") is a Delaware corporation with its principal place of business located in Massachusetts. AngioDynamics is engaged in the business of

researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the SmartPort.

4. Defendant Navilyst Medical, Inc. ("Navilyst") is a Delaware corporation with its principal place of business located in Marlborough, Massachusetts. Navilyst conducts business throughout the United States, including the State of Texas, and is a wholly owned subsidiary of AngioDynamics. Navilyst is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its medical devices, including the SmartPort.

## JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and cost.

6. Venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District and (b) Defendants' products are produced, sold to and consumed by individuals in the State of Texas, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.

7. Defendants have and continue to conduct substantial business in the State of Texas and in this District, distribute vascular access products in this District, receive substantial compensation and profits from sales of vascular access products in this District, and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to *in personam* jurisdiction in this District.

8. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Texas, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

**PRODUCT BACKGROUND**

9. In or about 2007, a company called Rita Medical Systems, Inc. received clearance via the 510(k) Premarket Notification Program from the Food and Drug Administration (FDA) to market and sell a product called Vortex® CT Port Access System.

10. Around the same time, Angiodynamics completed the acquisition of the assets and liabilities of Rita Medical Systems, Inc. and rebranded the subject product as SmartPort CT.

11. Defendants' Vascular Access Devices were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein.

12. The SmartPort is one of several varieties of port/catheter systems that has been designed, manufactured, marketed, and sold by Defendants.

13. According to Defendants, the SmartPort is a totally implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, and blood products.

14. The intended purpose of the SmartPort is to make it easier to deliver medications directly into the patient's bloodstream. The device is surgically placed completely under the skin and left implanted.

15. The SmartPort is a system consisting of two primary components: an injection port and a polyurethane catheter which includes additives intended to make it radiopaque.

16. The injection port has a raised center, or "septum," where the needle is inserted for delivery of the medication. The medication is carried from the port into the bloodstream through a small, flexible tube, called a catheter, that is inserted into a blood vessel.

17. The SmartPort is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

18. The product's catheter is marketed under the trade name Fluoromax and is comprised of a polymeric mixture of polyurethane and a barium sulfate radiopacity agent. The Fluoromax catheter was first trademarked by Horizon Medical Products in 2005 features a blue stripe which contains an even higher concentration of barium sulfate than the remainder of the lumen of the catheter.

19. Neither Horizon Medical Products nor AngioDynamics received clearance from the FDA to market the Fluoromax catheter, making such device *per se* misbranded pursuant to the Food, Drug and Cosmetic Act.

20. Barium sulfate is known to contribute to reduction of the mechanical integrity of polyurethane *in vivo* as the particles of barium sulfate dissociate from the surface of the catheter over time, leaving microfractures and other alterations of the polymeric structure and degrading the mechanical properties of the polyurethane.

21. Researchers have shown that catheter surface degradation in products featuring a radiopaque barium sulfate stripe is concentrated at the locus of the stripe.[1]

22. The mechanical integrity of a barium sulfate-impregnated polyurethane is affected by the concentration of barium sulfate as well as the heterogeneity of the modified polymer.

[1] See Hecker JF, Scandrett LA. Roughness and thrombogenicity of the outer surfaces of intravascular catheters. *J Biomed Mater Res*. 1985;19(4):381-395. doi:10.1002/jbm.820190404

23. Upon information and belief, Defendants' manufacturing process in designing and constructing the catheter implanted in Plaintiff involved too high a concentration of barium sulfate particles for the polymer formulation, leading to improperly high viscosity of the admixed polyurethane before polymerization and causing improper mixing of barium sulfate particles within the polymer matrix.

24. This defect in the manufacturing process led to a heterogeneous modified polymer which included weakened areas at the loci of higher barium sulfate concentration and led to fracture of the catheter.

25. Although the surface degradation and resultant mechanical failure can be reduced or avoided with design modifications (e.g. using a higher grade radiopacity compound and/or encapsulating the admixed polymer within polyurethane), Defendants elected not to incorporate those design elements into the SmartPort.

26. At all times relevant, Defendants misrepresented the safety of the SmartPort system, and negligently designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold the SmartPort system as safe and effective device to be surgically implanted to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products.

27. At all times relevant to this action, Defendants knew and had reason to know, that the SmartPort was not safe for the patients for whom they were prescribed and implanted, because once implanted the device was prone to fracturing, migrating, perforating internal vasculature and otherwise malfunctioning.

28. At all times relevant to this action, Defendants knew and had reason to know that patients implanted with a SmartPort port had an increased risk of suffering life threatening injuries, including but

not limited to: death; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; and perforations of tissue, vessels and organs, or the need for additional surgeries to remove the defective device.

29. Soon after the SmartPort was introduced to market, which was years before Plaintiff was implanted with her device, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the SmartPort was fracturing post-implantation and that fractured pieces were migrating throughout the human body, including to the heart and lungs. Defendants also received large numbers of AERs reporting that SmartPort was found to have perforated internal vasculature. These failures were often associated with reports of severe patient injuries such as:

a. hemorrhage.
b. cardiac/pericardial tamponade;
c. cardiac arrhythmia and other symptoms similar to myocardial infarction;
d. severe and persistent pain;
e. and perforations of tissue, vessels and organs; and
f. upon information and belief, even death.

30. In addition to the large number of AERs which were known to Defendants and reflected in publicly accessible databases, there are many recorded device failures and/or injuries related to the Defendants' implantable port products which were concealed from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program.

31. The FDA halted the ASR program after its existence was exposed by a multi-part investigative piece, prompting a widespread outcry from medical professionals and patient advocacy groups.[2]

32. Prior to the discontinuation of the ASR program, Defendants reported numerous episodes

[2] Christina Jewett, *Hidden Harm: Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 2019)

of failures of their implanted port/catheter products – including numerous episodes of catheter fracture – under the ASR exemption, thereby concealing them from physicians and patients.

33. Defendants were aware or should have been aware that the SmartPort had a substantially higher failure rate than other similar products on the market, yet Defendants failed to warn consumers of this fact.

34. Defendants also intentionally concealed the severity of complications caused by the SmartPort and the likelihood of these events occurring.

35. Rather than alter the design of the SmartPort to make it safer or adequately warn physicians of the dangers associated with the SmartPort, Defendants continued to actively and aggressively market the SmartPort as safe, despite their knowledge of numerous reports of catheter fracture and associated injuries.

36. Moreover, Defendants' warnings suggested that fracture of the device could only occur if the physician incorrectly placed the device such that undue catheter compression or "pinch-off" was allowed to occur. In reality, Defendants knew internally these devices were fracturing and causing serious injuries due to defects in the design, manufacturing and lack of adequate warnings.

37. The conduct of Defendants, as alleged in this Complaint, constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Defendants had actual knowledge of the dangers presented by the SmartPort System, yet consciously failed to act reasonably to:

a. Adequately inform or warn Plaintiff, her prescribing physicians, or the public at large of these dangers;
b. Establish and maintain an adequate quality and post-market surveillance system; or
c. Recall the SmartPort System from the market.

## SPECIFIC FACTUAL ALLEGATIONS AS TO CELA MORA

38. On or about March 28, 2019, Plaintiff underwent placement of the AngioDynamics SmartPort, lot number 5433493. The device was implanted by Dr. Velarde at Valley Baptist Medical Center in Harlingen, Texas, for the purpose of ongoing breast cancer treatment.

39. Defendant, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the SmartPort that was implanted in Plaintiff.

40. Defendant manufactured, sold, and/or distributed the Smartport to Plaintiff, through her doctors, to be used for delivery of chemotherapy.

41. On July 1, 2019, Plaintiff underwent surgery with Dr. Padginton at Valley Baptist Medical Center to remove the SmartPort and the fractured catheter.

48. At all times, the SmartPort was utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use and created procedures for implanting the product.

49. The SmartPort implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants, and in the condition directed by and expected by Defendant.

50. Plaintiff and her physicians foreseeably used and implanted the SmartPort, and did not misuse, or alter the SmartPort in an unforeseeable manner.

51. Defendants advertised, promoted, marketed, sold, and distributed the SmartPort as a safe medical device when Defendant knew or should have known the SmartPort was not safe for its intended purposes and that the product could cause serious medical problems.

52. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects.

53. In reliance on Defendants' representations, Plaintiff's doctor was induced to, and did use the SmartPort.

54. As a result of having the SmartPort implanted, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

55. Defendants' SmartPort was marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, and as a safer and more effective as compared to the traditional products and procedures for treatment, and other competing Vascular Access Devices.

56. The Defendants have marketed and sold the Defendants' SmartPort to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

57. The injuries, conditions, and complications suffered due to Defendants' SmartPort include but are not limited to hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels and organs; and even death.

58. Plaintiff brings this action pursuant to Tex. Civ. Prac. & Rem. Code § 16.064.

a. An action on the claims brought herein was first initiated in good faith on June 24, 2021, in the Superior Court for the Commonwealth of Massachusetts;

b. Such action was initiated within two years of Plaintiff's injury event and was, thus, timely filed;
c. Such action was dismissed for lack of personal jurisdiction on October 28, 2021;
d. The instant action is filed within sixty days of the aforesaid dismissal.

59. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with her medical providers, the nature of her injuries and damages, and their relationship to the Product was not discovered, and through reasonable care and diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

60. Plaintiff did not learn of Defendants' wrongful conduct until a time within the applicable statute of limitations. Furthermore, in the existence of due diligence, Plaintiff could not have reasonably discovered the Defendants' wrongful conduct, including, but not limited to, the defective design and/or manufacturing of the product until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

61. Defendants were negligent toward Plaintiff in the following respects:

a) Defendant failed to design and establish a safe, effective procedure for removal of SmartPort; therefore, in the event of a failure, injury, or complications it is difficult to safely remove SmartPort.

b) Defendants provided incomplete, insufficient, and misleading information to physicians in order to increase the number of physicians using SmartPort for the purpose of increasing their sales. By so doing, Defendants caused the dissemination of inadequate and misleading information to patients, including the Plaintiff.

62. The SmartPort was utilized and implanted in a manner foreseeable to Defendants.

63. The SmartPort implanted into Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by the Defendants.

64. At the time of her operation, Plaintiff was not informed of, and had no knowledge of the complaints, known complications and risks associated with SmartPort.

65. Plaintiff was never informed by Defendants of the defective and dangerous nature of SmartPort.

66. At the time of her implant, neither Plaintiff nor Plaintiff's physicians were aware of the defective and dangerous condition of SmartPort.

67. At the time of the injuries referenced herein, Plaintiff did not know that the surgery he underwent was due to a defect in these products.

68. It was not until a time within the applicable statute of limitations, that Plaintiff discovered Defendants' wrongful conduct. Furthermore, Plaintiff could not have reasonably discovered the Defendants' wrongful conduct, including but not limited to, the defective design and/or manufacturing of these devices until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

69. Plaintiff has suffered and will continue to suffer physical pain and mental anguish. Plaintiff has also incurred substantial medical bills and has suffered loss of other monies due to the defective product that was implanted in her body.

## FIRST CAUSE OF ACTION

## NEGLIGENCE

70. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

71. The Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling and conducting post-market surveillance of the SmartPort.

72. The Defendants failed to exercise due care under the circumstances and therefore breached

this duty by:

a. Failing to properly and thoroughly test the SmartPort before releasing the device to market, and/or failing to implement feasible safety improvements;
b. Failing to properly and thoroughly analyze the data resulting from any pre-market testing of the SmartPort;
c. Failing to conduct sufficient post-market testing and surveillance of the SmartPort;
d. Designing, manufacturing, marketing, advertising, distributing, and selling the SmartPort to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the SmartPort and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;
e. Failing to exercise due care when advertising and promoting the SmartPort; and
f. Negligently continuing to manufacture, market, advertise, and distribute the SmartPort after Defendants knew or should have known of its adverse effects.

73. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

74. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice so as to justify an award of punitive and/or exemplary damages.

## SECOND CAUSE OF ACTION

## STRICT PRODUCTS LIABILITY – FAILURE TO WARN

75. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

76. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the SmartPort, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of

harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

77. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the device was defective and presented a substantial danger to users of the product when put to its intended and reasonably anticipated use, namely as an implanted port/catheter system to administer the medications. Defendants failed to adequately warn of the device's known or reasonably scientifically knowable dangerous propensities, and further failed to adequately provide instructions on the safe and proper use of the device.

78. Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the SmartPort that was implanted into Plaintiff that the SmartPort posed a significant and higher risk than other similar devices of device failure and resulting serious injuries.

79. Defendants further knew that these devices were fracturing and migrating for reasons other than "pinch-off" caused by the physician's initial placement of the device

80. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the SmartPort; no reasonable health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.

81. The warnings, labels, and instructions provided by the Defendants at all time relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and misrepresented the risks and benefits and lack of safety and efficacy associated with the device.

82. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

83. The device, which was designed, manufactured, prepared, compounded, assembled,

processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

84. When Plaintiff was implanted with the device, Defendants Bard and BAS failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by the device, as discussed herein.

85. Defendants intentionally underreported the number and nature of adverse events associated with dislodgement and migration of the devices to Plaintiff's health care providers, as well as the FDA.

86. Neither Plaintiff nor her health care providers knew of the substantial danger associated with the intended and foreseeable use of the device as described herein.

87. Plaintiff and her health care providers used SmartPort in a normal, customary, intended, and foreseeable manner, namely as a surgically placed device used to make it easier to deliver medications directly into the patient's bloodstream. Moreover, Plaintiff's health care providers did not place or maintain the device incorrectly such that it caused the device to "pinch off" or otherwise malfunction.

88. Upon information and belief, the defective and dangerous condition of the device, including the one implanted into Plaintiff, existed at the time they were manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations. Upon information and belief, the device implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

89. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries, and economic damages in an amount to be determined at trial. In other words, had Defendants provided adequate warnings, Plaintiff and her physicians would not

have used the device.

**THIRD CAUSE OF ACTION**

**STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

90. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

91. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the SmartPort that was implanted into Plaintiff.

92. The SmartPort implanted in Plaintiff contained a manufacturing defect when it left Defendants' possession. The device differed from said Defendants' intended result and/or from other ostensibly identical unites of the same product line.

93. Upon information and belief, the SmartPort implanted in Plaintiff varied from its intended specifications.

94. Plaintiff and her health care providers used the SmartPort in a way that was reasonably foreseeable to Defendants.

95. The device's manufacturing defect was the direct and proximate cause of Plaintiff's serious physical injuries and economic damages in an amount to be determined at trial.

**FOURTH CAUSE OF ACTION**

**STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

96. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

97. The SmartPort implanted in the Plaintiff was not reasonably safe for its intended use and was defective with respect to its design.

98. The SmartPort was in a defective condition at the time that it left the possession or control of Defendants.

99. The SmartPort was unreasonably dangerous to the user or consumer.

100. The SmartPort was expected to and did reach the consumer without substantial change in its condition.

101. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

102. As a direct and proximate result of the SmartPort's aforementioned defects, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

**FIFTH CAUSE OF ACTION**

**BREACH OF IMPLIED WARRANTY**

103. Plaintiff incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

104. Defendants impliedly warranted that the SmartPort was merchantable and fit for the ordinary purposes for which it was intended.

105. When the SmartPort was implanted in the Plaintiff, it was being used for the ordinary purposes for which it was intended.

106. The Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the SmartPort implanted in him.

107. Defendants breached these implied warranties of merchantability because the SmartPort implanted in the Plaintiff was neither merchantable nor suited for its intended uses as warranted.

108. Defendants' breaches of their implied warranties resulted in the implantation of unreasonably dangerous and defective SmartPort in the Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

109. The SmartPort was sold to the Plaintiff's health care providers for implantation in patients, such as the Plaintiff.

110. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

## SIXTH CAUSE OF ACTION

## BREACH OF EXPRESS WARRANTY

111. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

112. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the SmartPort was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

113. The SmartPort does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.

114. At all relevant times, the SmartPort did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

115. Plaintiff, her physicians, and the medical community reasonably relied upon the Defendants' express warranties for the SmartPort.

116. At all relevant times, the SmartPort was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendants.

117. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

118. As a direct and proximate result of the breach of Defendants' express warranties, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

**FRAUDULENT CONCEALMENT**

119. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein. as if fully set forth herein.

120. Defendants fraudulently concealed information with respect to the SmartPort in the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the SmartPort was safe and fraudulently withheld and concealed information about the substantial risks of using the SmartPort;

b. Defendants represented that the SmartPort was safer than other alternative systems and fraudulently concealed information which demonstrated that the SmartPort was not safer than alternatives available on the market;

c. Defendants concealed that it knew these devices were fracturing and migrating from causes other than the manner in which the implanting physician implanted the device; and

d. That frequency of these failures and the severity of injuries were substantially worse than had been reported.

121. The Defendants had sole access to material facts concerning the dangers and unreasonable risks of the SmartPort.

122. The concealment of information by the Defendants about the risks of the SmartPort was

intentional, and the representations made by Defendants were known by Defendants to be false.

123. The concealment of information and the misrepresentations about the SmartPort was made by the Defendants with the intent that Plaintiff's health care providers and Plaintiff rely upon them.

124. Plaintiff and her physicians relied upon the representations and were unaware of the substantial risks of the SmartPort which the Defendants concealed from the public, including Plaintiff and her physicians.

125. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff has suffered, and will continue to suffer, severe physical pain and injuries which are permanent and lasting in nature, emotional distress, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, and economic loss as alleged herein. These damages have occurred in the past and will continue into the future.

126. The Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others, and to deter this Defendants and others from engaging in similar conduct in the future.

127. Had Defendants not concealed this information, neither Plaintiff's nor her health care providers would have consented to using the device in Plaintiff.

## PUNITIVE DAMAGES

128. Plaintiffs are entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare. Defendants intentionally and

fraudulently misrepresented facts and information to both the healthcare community and the general public, including Plaintiff and her health care providers, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the SmartPort. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the implantation of said product, and intentionally downplayed the type, nature, and extent of the adverse side effects of being implanted with the device, despite Defendants' knowledge and awareness of the serious and permanent side effects and risks associated with use of same. Defendants further intentionally sought to mislead health care providers and patients, including Plaintiff and her health care providers, regarding the cause of dislodgement and migration failures of the device.

129. Defendants had knowledge of, and were in possession of evidence demonstrating that, the SmartPort caused serious physical side effects. Defendants continued to market said product by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the device, notwithstanding Defendants' knowledge of the true serious side effects of the SmartPort, Defendants failed to provide accurate information and warnings to the healthcare community that would have dissuaded physicians from surgically implanting the SmartPort and consumers from agreeing to being implanted with the SmartPort, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and implanting the SmartPort.

130. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff suffered, and will continue to suffer, the injuries and damages described in this complaint.

WHEREFORE, Plaintiffs demands judgment against Defendants for compensatory, special, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the

Court deems proper.

## PRAYER

**WHEREFORE**, Plaintiff prays for judgment against each of the Defendants as follows:

a. Judgement be entered against all Defendant on all causes of action of this Complaint;

b. Plaintiff be awarded her full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded general damages according to proof at the time of trial;

d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;

e. Plaintiff be awarded punitive damages according to proof at the time of trial;

f. Awarding pre-judgment and post-judgment interest to the Plaintiff;

g. Awarding the costs and the expenses of this litigation to the Plaintiff.

h. For such other and further relief as the court may deem just and proper.

## DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: December 27, 2021

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